

K040032

FEB 27 2004

510(k) Summary for HomMed Central Station

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Morgan Consultants, Inc.
2018 North Durham
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Trade Name: HomMed Central Station, Version 3.3H

Predicate Device: HomMed Central Station

Common Name: Patient Vital Signs Monitor Viewing Station

Classification Name: Non-Invasive Blood Pressure Measurement System
Product Code: DXN

Intended Use:

Central Station's intended use is to retrospectively receive, display and store certain monitored physiological parameters received from adult and pediatric (over 12 years of age) patients within health care and home environments. Central Station, Version 3.3H includes a HL7 interface to transfer data from HomMed Central Station to vendor systems and storage media. The physiologic patient parameters available for retrospective display and evaluation include NIBP, pulse rate, SpO₂, temperature and weight. Additionally monitoring device data from optional commercial stand-alone products including glucometry, spirometry, prothrombin time, ECG and digital camera images can also be received, displayed and stored. The Central Station displays patient data and system alerts for review and interpretation by physicians and/or physician-supervised nurses. Central Station is a retrospective data monitor system and is not intended for emergency use or real-time monitoring.

Performance Data:

The HomMed Central Station is a software system that operates on a commercially available PC system with the minimum performance specifications consistent with typical PC hardware and equipment specifications. The HomMed Central Station is a software system that accepts data from the HomMed Sentry Patient Monitors. The software validation results demonstrated that the HomMed Central Station 3.3H System was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding patient monitors.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

Morgan Consultants, Inc.
c/o Tommie J. Morgan, Ph.D.
President
2018 North Durham
Houston, TX 77008

Re: K040032
Trade Name: Central Station, Version 3.3 H
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: January 07, 2004
Received: January 08, 2004

Dear Dr. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

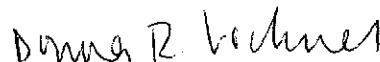
Page 2 – Tommie J. Morgan, Ph.D.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040032

Device Name: Central Station, Version 3.3H

Indications For Use:

The HomMed Central Station intended use is to retrospectively receive, display, and store certain monitored physiological parameters received from adult and pediatric (over 12 years of age) patients within healthcare and home environments. Central Station, Version 3.3H includes a HL7 interface to transfer data from HomMed Central Station to vendor systems and storage media. The physiologic patient parameters available for retrospective display and evaluation include NIBP, pulse rate, SpO₂, temperature, and weight. Additionally monitoring device data from optional commercial stand-alone products including glucometry, spirometry, prothrombin time, ECG and digital camera images can also be received, displayed and stored. The Central Station displays patient data and system alerts for review and interpretation by physicians and/or physician supervised nurses. Central Station is a retrospective data monitor system and is not intended for emergency use or real-time monitoring.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria D. Bachner
(Division Sign-Off)
Division of Cardiovascular Devices

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